22. (New) The regimen of claim 15 wherein said regimen has another phase with a daily dosage of norgestimate of 0.215 mg.

23. (New) The regimen of claim 15 wherein said regimen has another phase with a daily dosage of norgestimate of 0.2-0.3 mg.

24. (New) The regimen of claim 1 wherein said regimen consists of a 20-35 daily dosages for a cycle, and wherein the total norgestimate in said cycle is at least 8 mg.

25. (New)The regimen of claim 17 wherein said total norgestimate in said cycle is at least 12 mg.

26. (New)The regimen of claim 18 wherein said total norgestimate in said cycle is at least 20 mg.

REMARKS

In the Office Action, the Examiner rejected claims 2, 4-6 and 15-19 under 35 U.S.C. §112, ¶1 as failing to comply with the written description requirement. The Examiner also rejected claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over Elliesen et al.

Claim Rejection—35 U.S.C. §112 (Written Description)
Applicant Will First Address The Written Description Rejections

Turning to claim 2, the Examiner has rejected the claim on the basis that disclosing using "at least 0.5 mg" norgestimate and "at least 0.8 mg" norgestimate does not provide written description for the range 0.5-0.8. The Examiner contends that applicant cannot now claim a range between 0.5 and 0.8 because such a range would not have immediately envisaged by a person skilled in the art from the specification as originally filed. Applicant respectfully submits that the MPEP supports applicant's recitation of the 0.5-0.8 claim range.

Applicant's disclosure states as follows:

> where the regimens have at least one or more of the daily dosages having at least 0.5 mg of norgestimate, preferably at least 0.8,

> more preferably at least 1.2, and even more preferably at least 1.8, and most preferably at least 2.5 or more.

(Application page 35, lines 22-25). Thus, Applicant specifically disclosed the points of 0.5 mg norgestimate and 0.8 norgestimate. Drawing the points on a numerical line:

0 0.5 0.8 1.2 1.5 1.8 2.0

Applicant discloses 0.5 and greater as part of his invention. Applicant disclose the point of 0.8 as part of his invention. Based on the disclosure in the specification, a person skilled in the art would understand that applicant's invention included the range of 0.5 to 0.8. The MPEP states:

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003). MPEP 2163.

In fact, the MPEP specifically provides an examples in a section entitled "Range Limitations" which supports Applicants position that the range of 0.5-0.8 mg is appropriate. The MPEP discusses an example where the original specification included a range of "25%-60%" and specific examples of 36% and 50%. The applicant in that example submitted a new claim to 35-60%. The MPEP states that the claim met the written description requirement even though 36% was not identified as a lower limit for a range. The written description requirement was met even though the specification did not say "at least 35%" or identify the "36%" as a lower limit to arrange. Despite the 36% simply being a point that the applicant had identified, the MPEP states that a range of "between 35%-60%" was completely appropriate. The MPEP states:

> With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191

> USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement. MPEP 2163.05

In the present application, the applicant discloses 0.5 as a specific point in his invention. Applicant further discloses 0.8 as a specific point in his invention. Moreover, the range between 0.5 and 0.8 is disclosed as part of applicant's invention. A person skilled in the art would readily realize that the range between 0.5 and 0.8 was part of Applicant's invention. Thus, pursuant to the MPEP, applicant can claim this range and meet the written description requirement.

Similarly, with respect to claim 4, Applicant's claim range of 0.8-1.2 mg is proper pursuant to the same MPEP section. Support is found in Applicant's specification at page 35, lines 22-25 where the points 0.8 and 1.2 mg are disclosed and the range between is disclosed as part of applicant's invention.

The support for claim 5 is found on page 5 of the application, page 54 of the application, line 8, specifically with respect to norgestimate hormonal regimens.

Claim 6 has been amended to recite a range of 1.0-2.0 mg. Support for this limitation is found on page 54, lines 1-8. Applicant's specification at page 54, lines 1-8 discloses the points 1.0 and 2.0 and the range between is disclosed as part of applicant's invention.

Applicant has amended claim 15 to eliminate the phrase: "another phase having daily dosage of norgestimate less than 0.25 mg." Support for the amended claim is found at page 35, line 23.

Applicant has amended claim 16 to delete the phrase "less than 0.25 mg." Applicant has added the phrase claim limitation "0.2-0.3 mg" for the other phase of the multi-phasic regimen.

Support for this claim limitation is found at page 48, lines 1-4, where there is a specific reference to 200-300 μg norgestimate, or 0.2-0.3 mg norgestimate. In addition, that same paragraph provides support for "at least 800 μg norgestimate. (Page 48, line 14).

With respect to claims 17-19, applicant has amended claim 17 to recite a 28 day regimen of daily dosages. Page 36 lines 4-6 supports the 28-day limitation. Claims 18 and 19 depend from claim 17.

Applicant has added new claims 20-26. The support for claims 20-22 comes in part from Table 2 with respect to the regimens in the art known for tri-phasic norgestimate. The application clearly contemplates taking known OCP compositions and changing them to obtain the benefits of the invention. The invention also describes taking such known hormonal regimens and increasing one of the phases to a higher level. In the application at pages 29-30, Applicant states that the invention includes expanding the clinical usages of progestin drugs beyond the current use of these drugs as oral contraceptives. Applicant specifically states that these can be accomplished by altering the dosage of the progestin product. Applicant specifically states:

> This can be accomplished in a number of ways, including altering the dosage of the progestin product, the type of progestin product, the ratio progestin product, the estrogen product, or the timing of administration. Also, specifically contemplated is administration of a progestin product and doses higher than those currently used for contraception."

Application page 30, lines 5-8. Applicant specifically describes ways of altering OCP formulations, including multi-phasic OCP regimens where at least one of the daily dosages has at least 0.5 mg norgestimate. (Application page 35, 19-26).

MPEP §2163.02 states as follows:

> The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective

> standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

Here, a person skilled in the art would certainly understand that Applicant's invention included starting with known OCP formulations and altering them in terms of progestin dosage as taught by the application. One product that is described in Table 2 is the tri-phasic norgestimate with dosages 0.18, 0.215 and 0.25 mg norgestimate. The application specifically states that one can have a multi-phasic norgestimate regimen where one of the phases now has 0.5 mg norgestimate. Thus, a person skilled in the art would immediate envisage that this was part of the invention disclosed in the application.

With respect to new claim 23, 200-300 μg norgestimate is described at page 48, line 4.

With respect to new claims 24-26, the specification discloses regimens of 20-35 days several times in the specification (see, for example, page 54, line 20 and page 55, line 10).

Claim Rejection – 35 U.S.C. §103

The Examiner has rejected claims 1-19 under 35 U.S.C. §103 as being unpatentable over Elliesen. Applicant submits that claims 1-19 are patentable over Elliesen.

In applicant's prior response, applicant pointed out that Elliesen does not disclose an estrogen component "in the range of 20-35 mcg ethinyl estradiol." Elliesen specifically teaches an EE dosage of 5-15 mcg. Applicant also notes that Elliesen teaches at a goal is to minimize the dosage of estrogen. Applicant respectfully submits that the Examiner has not cited to any motivation to go any higher than the 15 mcg of EE taught by Elliesen.

The Examiner has directed Applicants attention to Elliesen at the paragraph bridges pages 14-15. However, Elliesen is not stating an exemplary dosage. Rather, Elliesen's full sentence states that specific examples of estrogens and then provides the appropriate dosage ranges for each estrogen. Elliesen never states that the dosages provided are merely exemplary. The full quote from Elliesen states as follows:

> Examples of estrogens which can be employed in this invention (dosages shown are oral; transdermal dosages will vary therefrom in accordance with the absorption efficacy of the vehicle employed) are ethinyl estradiol and mestranol (5 - 15 mcg/day), estradiol and their esters, e.g. valerate, acetate, benzoate and undecylate (0.5 - 4 mg/day), estriol, estriol succinate, polyestriol phosphate (2 - 8 mg), estrone, estrone sulfate and conjugated estrogens (0.3 - 1.2 mg/day).

Elliesen does not teach that the dosages are exemplary. Rather, Elliesen teaches that the estrogens are exemplary, and then lists specific dosage ranges for each estrogen, not exemplary dosages.

The Examiner has cited MPEP 2123 stating that "disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments." However, that MPEP section is simply referring to situations where the prior art has specific disclosures which are not preferred. Those specific disclosures can be relied on for prior art rejections. The MPEP states:

> A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). *See also Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 14516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

Thus, the embodiment in the cited example of a "carrier data signal" was less than optimal. However, that teaching did not eliminate the fact that a single carrier data was disclosed and thus was prior art.

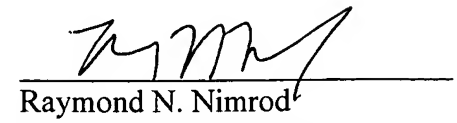
Here, Elliesen does not disclose 20 mcg of EE or higher and then teach away from it. Elliesen discloses one and only range for EE, namely, 5-15 mcg. Elliesen provides absolutely no disclosure of a dosage above 15 mcg. The Examiner cannot simply use a disclosure of an estrogen with a dosage of 5 to 15 mcg to say that it teaches other dosages.

The Examiner cites page 2, ¶4 of Elliesen. However, this page does not provide any motivation to go above 15 mcg. Elliesen is simply stating that women have different needs for HRT regimens and therefore discloses an invention where the dosage can be altered. Having made that statement, Elliesen makes no suggestion whatsoever that the dosage should or can exceed 15 mcg EE. Rather, Elliesen teaches a range of 5-15 mcg EE.

The Examiner also cites MPEP 2144.05 which states that the normal desire of scientists to improve can provide motivation to discover optimum or workable ranges from the prior art. Here, however, this is not a situation where a scientist is motivated to find the optimum range from the broader range disclosed by Elliesen. Rather, the claimed range of Applicant is completely outside of Elliesen's range.

For these reasons, applicant respectfully submits that the pending claims are ready for allowance.

Respectfully submitted,



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